K131028

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510(k) Summary

APR 10 2014

The following summary is provided in accordance with 21 CFR 807.92:

Date: 10 Apr 2014

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Trade/Device Name: PENTAX Video Bronchoscopes (EB Family)

Model Numbers: EB-1970TK, EB-1170K, EB-1570K, EB-1575K, EB-1970K, EB-1975K, EB-1990i

Common/Usual Name: Bronchoscope

Regulation Number: 21 CFR Part 874.4680
Regulation Name: Bronchoscopes (Flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ

Predicate Device: OLYMPUS Bronchoscope BF Type 1T180 (K061313; dated Aug 30 2006)

Regulation Number: 21 CFR Part 874.4680
Regulation Name: Bronchoscopes (Flexible or rigid) and accessories
Regulation Description: Endoscope and accessories
Regulatory Class: Class II
Product Code: EOQ

Device Description:

The PENTAX Video Bronchoscopes (EB Family); Model Numbers: EB-1970TK, EB-1170K, EB-1570K, EB-1575K, EB-1970K, EB-1975K, EB-1990i are used with a Video Processor. The PENTAX Video Bronchoscopes (EB Family) are composed of the following main parts: an Insertion Portion, Control Body and PVE Connector.

The Insertion Portion is inserted into the body cavity of patient. The Insertion Portion includes the Distal End and Bending Section. The Objective Lens, Light Guide, and Instrument Channel are located on the Distal End of the Insertion Portion.

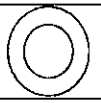
The Control Body is held by the user's hand. The Control Body includes the Angulation Control lever, Suction Cylinder, Suction nipple, Remote Button, and Instrument Channel Inlet. The Suction Control Valve is attached to the Suction Cylinder. The Inlet Seal is attached to the Instrument Channel Inlet. The Bending Section is bent by the Angulation Control lever to operate the endoscope angulation. The Suction Control System is used to suction the fluid and air in body cavity from the Instrument Channel. When the Suction Control Valve is pushed, the fluid and air are suctioned. The Remote Button is used to operate the function of video processor and external device from the control body, as necessary. Endotherapy Device such as Biopsy Forceps is inserted from the Instrument Channel Inlet into the body cavity through the instrument channel.

The PVE Connector is connected to the Video Processor via an Electrical Contacts. The PVE Connector includes the Electrical Contacts and Light Guide Plug. The Light Guide Plug is connected to the Light Source inside the Video Processor. The Light Guide of the Distal End is used to illuminate the body cavity by light which is carried through the Light Carrying Bundle. The Light Carrying Bundle guides the light from Light Guide Plug which is connected to the Light Source. The CCD built into the Distal End receives reflected light (image data) from the body cavity, and sends the image data to the Video Processor through the video cable. The image data are converted into the image signal by the Video Processor, and the image inside the body cavity is displayed on the Monitor.

The PENTAX Video Bronchoscopes are reusable semi-critical devices. Since they are packaged non-sterile, they must be high-level disinfected or sterilized BEFORE initial use. Prior to each subsequent procedure, they must be subjected to an appropriate cleaning and either high-level disinfection or sterilization processes.

The PENTAX Video Bronchoscopes (EB Family) Accessories and Component List:

Type	Product No.	Model name	Description	Image/Picture	Compatible with						
					EB-1970TK	EB-1170K	EB-1670K	EB-1970K	EB-1675K	EB-1975K	EB-1990I
Accessory for Reprocessing	CS8015ST	Cleaning Brush (Long)	Brush used for cleaning the endoscope channels. The brush cleans the Instrument Channel by being inserted from the Instrument Channel located at the Control Body and through the distal end of the endoscope.		Y	N	Y	Y	Y	Y	N
	CS3010S	Cleaning Brush (Long)	Brush used for cleaning the endoscope channels. The brush cleans the Instrument Channel by being inserted from the Instrument Channel located at the Control Body and through the distal end of the endoscope.		N	Y	N	N	N	N	Y
	CS8002SN	Cleaning Brush (Short)	Brush used for cleaning the endoscope channels. The brush cleans the Suction Channel by being inserted from the Suction Nipple located at the Control Body and through the suction cylinder of the endoscope. Also, cleans the endoscope Suction Channel by being inserted through the Suction Cylinder located at the Control Body and through the junction with the Instrument Channel.		Y	Y	Y	Y	Y	Y	Y
	CS-C3S	Cleaning Brush	Brush used for cleaning the endoscope cylinders. The brush is used to clean the Suction Cylinder located at the Control Body.		Y	Y	Y	Y	Y	Y	Y
	OF-B155	Cleaning Adapter	It is used during reprocessing to seal the Suction Cylinder located at the Control Body in order to fill the chemical solution inside the channel.		Y	Y	Y	Y	Y	Y	Y
	OF-C5	Ventilation Cap	The cap for communicating the internal and external parts of the endoscope by being attached to the Port located on the endoscope Connector. During the air transportation, it prevents the damage from the pressure difference of the internal and external parts of the endoscope.		Y	Y	Y	Y	Y	Y	Y
	OE-C9	Soaking Cap	During reprocessing, it prevents the chemical solution contacting the Electrical Contacts by being attached to the endoscope Electrical Contact.		Y	Y	Y	Y	Y	Y	Y

Accessory	OF-Z11	Silicone Oil	Lubricant applied to reduce wearing of O-ring attached to the Suction Control Valve (OF-B179).		Y	Y	Y	Y	Y	Y	Y
	OF-Z5	Bite Block	It is used when the endoscope is inserted per orally to the patient. The patient will bite on it so that he/she does not bite the insertion tube.		Y	Y	Y	Y	Y	Y	Y
	VE-B2	Carrying Case	Carrying case used for transporting the endoscope.		Y	Y	Y	Y	Y	Y	Y
Endoscope Component	OF-B179	Suction Control Valve	It is used by being attached to the Suction Cylinder located at the Control Body. Discharge from inside the patient body is suctioned by attaching the tube of the external suction pump, and depressing the button to communicate the suction pump and the endoscope distal end.		Y	Y	Y	Y	Y	Y	Y
	OF-B190	Inlet Seal	Seal that prevents the suctioned stuff coming out of the Instrument Channel Inlet during the use of suction function. It is attached to the Instrument Channel located at the Control Body. During the reprocessing, it seals the Instrument Channel Inlet in order to fill the chemical solution inside the channel.		Y	Y	Y	Y	Y	Y	Y
Replacement Part	OF-B181	O-ring set	Spare O-ring parts that are attached to the Suction Control Valve (OF-B179).		Y	Y	Y	Y	Y	Y	Y

NOTE:

- Accessories and components listed above are included as part of this 510(k) submission
- For Cleaning, Disinfection, and Sterilization refer to Instructions for Use (Reprocessing), Section 1-3

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Intended Use:

The PENTAX Video Bronchoscopes (EB Family) have been designed to be used with a PENTAX Video Processor (including Light source), documentation equipment, video monitor, endo-therapy accessories (such as biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the airways and tracheobronchial tree.

Summary of Technology Characteristics

The PENTAX Video Bronchoscope has the same fundamental technology and operating principles in comparison to those of the predicate device, including same intended use, design technological characteristics, such as Insertion Portion, Control Body and fiberoptics illumination. The minor differences in the Depth of Field, Distal end width, Insertion Tube width, instrument channel width, and Total Length between two devices do not impact the intended use, and do not raise different questions of safety and effectiveness and that the device is as safe and effective as a legally marketed device.

Safety and Performance Data (Non-clinical tests)

Design Verification and Validation testing has been performed in accordance with Design control per 21 CFR Part 820.30. The performance of the EB Family Master Device (EB-1970TK) were evaluated using the appropriate methodology as specified in the following FDA recognized consensus standards in conjunction with our in-house test protocols and use of external testing laboratories:

1. IEC 60601-1:1988+A1:1991+A2:1995 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-1:2000 Medical electrical equipment- Part 1-1: General requirements for safety- Collateral standard: Safety requirements for medical electrical systems
3. IEC 60601-1-2:2001+A1:2004 Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
4. ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
5. ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
6. ISO 10993-10:2010 Biological evaluation of medical devices - Part 10:Tests for irritation and skin sensitization
7. IEC 60601-2-18:1996+A1:2000 Medical electrical equipment- Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

8. ISO 8600-1:2005 Optics and photonics - Medical endoscopes and endotherapy devices - Part 1: General requirements
9. ISO 8600-3:1997+A1:2003 Optics and optical instruments –Medical endoscopes and endoscopic accessories - Part 3: Determination of field of view and direction of view of endoscopes with optics
10. ISO 8600-4:1997 Optics and optical instruments -Medical endoscopes and certain accessories - Part 4: Determination of maximum width of insertion portion
11. AAMITIR12:2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers
12. AAMITIR30:2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
13. ANSI/AAMI TIR79:2010 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
14. IS013485:2003 Medical devices - Quality management systems - Requirements for regulatory purposes
15. ISO 14971:2007 (corrected version): Medical devices -Application of risk management to medical devices
16. IEC 60601-1-4:2000 Ed. 1.1 Medical electrical equipment- Part 1-4: General requirements for safety- Collateral Standard: Programmable electricalmedical systems
17. IEC 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
18. IEC 62366:2007 Medical devices -Application of usability engineering to medical devices
19. IEC 62304:2006 Medical device software- Software life cycle processes
20. IEC 604171SO 7000-DB-12M:2004 Graphical symbols for use on equipment-12-month subscription to online database comprising all graphical symbols published in IEC 60417 and ISO 7000
21. ISO 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
22. IEC 60878:2003 Graphical symbols for electrical equipment in medical practice

The PENTAX Video Bronchoscope (EB Family) Master Device (EB-1790TK) test results satisfy the acceptance criteria specified by the above applicable standards.

Biocompatibility Test

Biocompatibility of direct and indirect contact materials were confirmed by testing the Cytotoxicity, Sensitization and Intracutaneous Reactivity for the surface device, mucosal membrane contact less than 24 hours duration device category in accordance with the ISO 10993-1, 5, and 10 Biological evaluation of medical devices standard and the FDA's guidance the Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'.

Reprocessing Validation

Simulated use conditioned test samples were used in the Cleaning validation and High Level Disinfection validation studies for validating the effectiveness of the reusable Bronchoscope Reprocessing procedures/methodology in accordance with the FDA's Draft Guidance for Industry and FDA Staff Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling distributed in May 2, 2011, AAMI TIR 12:2010 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for device manufacturers, AAMI TIR 30:2011 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices, and AAMI TIR79:2010 Comprehensive guide to steam sterilization and sterility assurance in health care facilities. All the study results satisfy the acceptance criteria specified by the above applicable standards.

In addition, the Reprocessing Instructions (Manual) were validated based on the FDA's Draft Guidance for Industry and FDA Staff Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling distributed in May 2, 2011. The validation confirmed that the EB Family Bronchoscope Reprocessing Instructions are complete, understandable, and can reasonably be executed by the user. Also, the optional sterilization using the FDA cleared (K042116) STERRAD NX System for EB-1575K, EB-1975, and EB-1990i has been validated per the manufacturer's specification and in accordance with AAMI TIR79:2010 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

EMC and Electrical Safety

The acceptable level of Electromagnetic compatibility (EMC) and Electrical Safety (ES) for the EB Family Master Device (EB-1790TK) were confirmed by testing in accordance with the IEC 60601-1; IEC 60601-1-2; IEC 60601-1-4; IEC 60601-1-6; Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, Safety requirements for medical electrical systems, Electromagnetic compatibility - Requirements and tests; and IEC 60601-2-18:1996+A1:2000 Medical electrical equipment- Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.

Substantial Equivalence discussion:

The PENTAX Video Bronchoscope has the same intended use, fundamental technology and operating principles including design technological characteristics, such as Insertion Portion, Control Body and fiberoptics illumination in comparison to those of the predicate device. The minor dimensional differences in the Depth of Field, Distal end width, Insertion Tube width, instrument channel width, and Total Length between two devices do not impact the intended use, and do not raise different questions of safety and effectiveness and that the device is as safe and effective as a legally marketed device.

Conclusion:

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The PENTAX Medical Company believes that the PENTAX EB Family of Scopes as indicated in this special 510(k) premarket notification submission is to be as safe, as effective and substantially equivalent in performance to the above identified cleared predicate device/system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 10, 2014

PENTAX Medical Company
Mr. Krishna Govindarajan
Regulatory Manager
3 Paragon Drive
Montvale, NJ 07645-1782

Re: K131028
Trade/Device Name: PENTAX Video Bronchoscopes (EB Family)
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscopes (Flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: March 7, 2014
Received: March 10, 2014

Dear Mr. Govindarajan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131028

Device Name: PENTAX Video Bronchoscopes (EB Family)
Model Numbers: EB-1970TK, EB-1170K, EB-1570K, EB-1575K, EB-1970K, EB-1975K, EB-1990i

Indications for Use:

The PENTAX Video Bronchoscopes (EB Family) have been designed to be used with a PENTAX Video Processor (including Light source), documentation equipment, video monitor, endo-therapy accessories (such as biopsy forceps) and other ancillary equipment for endoscopy and endoscopic surgery within the airways and tracheobronchial tree.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

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